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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,291	01/08/2002	Christian John Cook	P67120US0	2439

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

09	Application No. 936291	Applicant(s) Cook
	Examiner McLey	Group Art Unit 1616
		15

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/3/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 52-59, 61, 64, 67-84, 93-98 is/are pending in the application.
- Of the above claim(s) 58, 89, 81-84, 94-98 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 52-57, 61, 64, 67-80, 93 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 52-59, 61, 64, 67-84, 93-98 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 14
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Receipt is acknowledged of Request for time, amendment and IDS each of 1/31/03, respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58, 59, 81-84, 94-98 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

New claims consist of only the 2 anti-stresses, no amino acid is required, contrary as constitutes applicant's elected Group III. Claims 58, 59 are non-elected, as mifepristone is an antiprogesterin, thus, not one of claim 53. There is no antecedent basis for the elected pair in claim 58, 59.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67-69; 76, 53, 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At ~~53-56~~ - what are corticotrophin Reducing – inhibitors?

ACTH should be spelled out at first appearance in claim (53), 67-69 are compositions, but the claim~~g~~ is to dosages, thus, absent a concentration or amount range, the composition is of indeterminate concentration of agents. Claim 76 is to a trade name; the generic description should be in the claim, and competent support

provided, if not sufficiently described in the specification. Likewise for CRH 9-41, of claims 55.

Claims 52-54, 61, 64, 67-80, and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims utilize functional language open to wide interpretation, providing speculation as to the intended meets and bounds of the claims. "Anti stress" can be a food; people are known to reduce stress by eating. The same overgeneralization can be construed as intended for claims 70, 72, 77, and 78. "Slow release" absent any time frame or environment of use – (injection i.v., bolus, implant or pour on) impedes understanding of intended time frame. Claims to a composition: an "antibiotic", and "oligosaccharide" does not. The specific components (claims 71, 74, 76, and 79) do. We will not hold to this position for claim 80. However, claim 80 is unclear if a combination of the diluents or – "or" a solubilizer, permits 2 diluents, but does not permit of diluents and a solubilizer. The functional language of anti stress, absent identification of compounds, permits no identification of specific compositions – any compound, as shown above with food as an agent; capable of function even as a side effect, according to claim 53; the antiprogestations of 54, and of 58 would meet the claimed language, thus found with in the pages of Goodman and Gilman, but not provide and identifiable 36 composition in accord with the instant inventive concept see for example p.1 of WO 82/00411 – stress can be injury, illness, sepsis-. As to claim 93, we do not find support evident for the compositional form of elected species, among those claimed in 93; all of

which were identified originally as separate groups. Applicant is requested to identify the delivery form in accord with the composition of claim 61 with metyrapone and mifepristone if supported in the specification. If the elected species fails to constitute one of the forms of claim 93, 93 will be withdrawn from consideration. Finally, compounds of claim 71 and 79, (the complex) are not identifiable in CAS; please provide structures.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-57, 61, 67, 68, 80, 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over ~~Polack~~ ^{Black} Byrn – WO 82/0041 in view of Walser-WO 95/30418 or ~~TO~~ ^{TO}-et al 5937790, and D Aley et al '93.

Black Byrn shows stress, equivalent to injury (page 10, line 8-10, page 2, line 1, P6, line 28-34) immune competency, trauma, sepsis, illness, treatable with valine, Leucine and isoleucine (line 16, 17 P. 10) claim 1, 3, 4). However, assed anti-stress agents (p. 6, line 6-26) while providing anti stress compositions pharmaceutically acceptable diluents, excipients and carriers – infusion solutions) (P. 7, top, P. 8, top), with pH adjusters (P.11, line 18-25), - constitute only nutrients; Drugs were not specified. Crasler also deals with stress immune competency (P.3 top) and shows treatment with compositions including glucocorticoid suppressors (P.4) inclusive of mifepristone and (p.7) and Metyrapone (P.8) orally (P.9, bottom) or injected, at .25g –

1g daily, for human (p.10, lines 28-30), thus for 220 # man, .01 g/kg/dose of a.25g composition. No compositions are described.

It presents composition which also is directed to stress and immune competency (col. 1) liner 40-50). Here we find a vitamin C focus; with adjuvant (col. 6, lines 42-65) in feed forms (col. 6, line 66 – line 4) with drugs. The instant drugs are not mentioned, but the oligosacharide, as a vitamin C complex (line 41, col. 6) is. Prompters (col. 6, line 49-65) and Performa use enhances are also envisioned.

D Ayley shoe advantageous use of metyrapone to treat wounds (P. 959), although a rebound effect was noticed, (bottom col. 1, of page 959); suggesting controlling dosage administration and maintain. Dosage used was 65 mg/kg, that of the instant claims 67, 68 (p. 958, top).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a natural, safe stress treatment composition to use one of Black Burn, modified to optimize treatment utilizing known drugs, as shown by D Aley, I to and Walser, all effective in stress treatment.

It has not clearly been established by objective showing of some unobvious and/or unexpected results that the administration of the particular form of active, carrier, or the particular form of stress, to be treated provides any greater level of prior art expectation as claimed. Further, applicant has showed no criticality as to the ingredient actives concentrations, ratios or Application.

The selection of each ingredient and form thereof is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each

additive ingredient to optimize the effects desired, and the use of such ingredient for the functionality for which they are known to be used is not a basis for patentability.

Claims 52, 53, 61, 64, 67-69, 75, 80 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Schafer et al 5728675.

Schaefer address stress (summary) providing. The instant amino acid mix (col. 2, line 44-48) col. 4, (a)) with the instant anti stress agent"; vitamins, minerals, including vitamin C (col. 4, lines 33-38) and electrolytes (col. 3, (a)) in solid form or drench (col. 5, line 66-line 5, col.66), antigluta miner Gus (f), serotinerdis (d) gamma amino – potentiators (d) and energy sources (lines 38-53). The dosages are of the instant: electrolytes are 2-40g/500 kg annual (col. 6, lines 33-48). Performance enhances are present. Thryptophane, methionine (col. 5, lines 41, 42). Carriers and delivery forms are as instantly claimed (col. 7).

Applicant's arguments with respect to claims 52-59, 61, 64, 67-84, 93-98 has been considered but is moot in view of the new ground(s) of rejection.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703)308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Levy/LR
April 3, 2003



NEIL S. LEVY
PRIMARY EXAMINER